

## REMARKS

The claims have been amended to make explicit the steps involved in the screening methods claimed. Support for the specific methods of testing is found on page 17 of the specification, lines 7-24.

The protocol for identifying antagonists as opposed to agonists is well-known in the art and need not have been spelled out in the specification. It is well known that it is necessary to employ an agonist to activate the channels in order to test for antagonists, so that their effect on activation is measured. Accordingly, no new matter has been added and entry of the amendment is respectfully requested.

### Rejection of Claim 21 Under 35 U.S.C. § 112, Second Paragraph

The Office objects that the “ $\alpha_1$  subunit of an mammalian T-type calcium channel” does not define the metes and bounds of the invention. This basis for rejection is somewhat puzzling to applicants. As described in the specification, the basic structure of calcium channels in general is well known in art (see, for example, page 3, first full paragraph). It should be necessary to say no more than this, in order to obviate the rejection. It is as if reference to the “light chain of an immunoglobulin” were questioned as indefinite, on the ground that no one would know what it meant. Those of ordinary skill in the art who are familiar with calcium channels know exactly what the  $\alpha_1$  subunit means and would have no difficulty distinguishing it from the remaining known components of calcium channels - the  $\alpha_2\delta$  and  $\beta$  subunits for all high-threshold channels and, in addition, the  $\gamma$  subunit for L channels. If the difficulty faced by the Office resides in distinguishing T-type calcium channels from other types, this is addressed on page 2-3 of the specification, bridging paragraph, which demonstrates that, again, those familiar with calcium channels know exactly what is meant by this term and can distinguish T-type channels from the remaining types by the voltage profile exhibited. It is as if the Office were to

question the distinction between  $\delta$ ,  $\kappa$ , and  $\mu$  opioid receptors, when everybody in the field knows exactly how to distinguish these types.

Respectfully, it is believed that the Office has not taken account of the description in the specification of the known art concerning calcium channels and therefore, this basis for rejection should be withdrawn.

As to the objection to claim 21 in terms of what parameters are used to evaluate the interaction, it is believed that the proposed new claims obviate this basis for rejection. The format suggested by the Office has been followed.

Rejection of Claim 21 Under 35 U.S.C. § 101 and 35 U.S.C. § 112, First Paragraph

The basis for this rejection is, apparently, that the utilities described for the methods for the invention are not specific or substantial or well established. Applicants note that the Office states that “neither the specification nor the art disclose any disease states treatable by the novel polynucleotides of instant invention or polypeptides encoded by them.” Of course, this is not relevant to the presently claimed invention. The Office goes on to state that neither the specification nor the art of record disclose any instances where blocking any effects of said polynucleotides or polypeptides encoded by them reduces the effect of a disease state and that asserted utilities are only methods of treating unspecified, undisclosed diseases or conditions.

This, of course, is not true. And this assertion is the basis for the rejections, both under § 101 and § 112.

It is both described in the specification and known in the art that T-type calcium channels are associated with a multiplicity of conditions, and that blocking the activity of these channels or activating them will have, therefore, an effect on these conditions. It is further known in the art that although T-type channels come in a variety of forms, they are sufficiently similar that a compound which interacts with one as an agonist or antagonist will thus interact with all the rest.

Therefore, a compound which is useful in treating a condition modulated by one type of T-type channel will also be useful in treating a condition modulated by another T-type channel.

Enclosed herewith is the Declaration of Dr. Terrance Snutch, an expert in this field, demonstrating that the nexus between T-type calcium channels and specific and substantial disease states is well known in the art and that a screen which detects successfully binding, agonist or antagonist compounds with regard to one T-type channel is dispositive of the interaction of that compound with all other T-type channels. Accordingly, the identification methods claimed are useful in identifying compounds which are likely to be successful in treating convulsive neuronal disorders such as epilepsy, in treating cardiac conditions, and in treating infertility, for example. These utilities are clearly substantial, specific to T-type channels and credible as verified by the art cited in Dr. Snutch's declaration.

#### CONCLUSION


The claims have been made more explicit, and the definite nature of the term " $\alpha_1$  subunit of a T-type receptor" has been explained. Further, the Declaration of Dr. Snutch verifies that compounds identified by the methods of the invention have "real world" utility and thus the claimed invention is useful as required by 35 U.S.C. § 101, and applicants have taught how to use their invention in compliance with 35 U.S.C. § 112, first paragraph. Accordingly, claims 25-33 are in a position for allowance and passage of these claims to issue is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 381092000720. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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